REMARKS

The Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures mailed June 7, 2006, concluded that a sequence listing is required in the instant application. For the reasons stated below, Applicants assert that the disclosures of the instant Specification do not fall within the scope of the sequence listing requirements set forth in 37 C.F.R. §§ 1.821-1.825, as further explained in MPEP § 2422.

According to 37 C.F.R. § 1.821(a), "Nucleotide and/or amino acid sequences as used in Sec. Sec. 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. <u>Branched sequences are specifically excluded from this definition</u>." (emphasis added)

Applicants note that the sequences disclosed on pages 17, 19, 20, 41, 47 and 123 are in fact <u>branched</u> and therefore fall outside the scope of the requirements of 37 C.F.R. §§ 1.821-1.825. For example, on page 17 of the Specification, R¹-Lys(X)-R²-Lys(Y), the moieties "X" and "Y" are attached to the side chains of the lysine residue and are not part of a linear backbone. Therefore, the subject molecules are in fact branched sequences that are not subject to the sequence listing requirement. Similarly, on page 41, acetyl-Cys-Lys(DTPA)-Tyr-Lys(DTPA)-NH₂ also indicates a <u>branched</u> sequence, wherein both DTPA moieties are attached to the side chains of lysine residues and are not part of a linear sequence.

Further, according to 37 C.F.R. § 1.821(a)(2), "Those amino acid sequences containing D-amino acids are not intended to be embraced by this definition." Applicants note that the sequences disclosed on pages 17, 19, 20, 41, 47, 64 and 123 may comprise one or more D-amino acids and are thus outside the scope of 37 C.F.R. §§ 1.821-1.825. See, for example, page 19, lines 1-2, which recite that, "Also, it may be desirable to create a peptide that includes one or more D-amino acids."

Finally, according to 37 C.F.R. § 1.821(a)(2), "Any peptide or protein that can be expressed as a sequence using the symbols in WIPO Standard ST.25 (1998), Appendix 2, Table 3 in conjunction with a description in the Feature section to describe, for example, modified linkages, cross links and end caps, non-peptidyl bonds, etc., is embraced by this definition." Applicants note that the sequences disclosed on pages 17, 19, 20, 41, 47 and 123 contain one or more moieties that <u>are not</u> amino acids that may be expressed using the

symbols in WIPO Standard ST.25 (1998), Appendix 2, Table 3. The cited WIPO Table is incorporated into MPEP § 2422, incorporated herein by reference. Nowhere does WIPO Standard ST.25 (1998), Appendix 2, Table 3, or WIPO Standard ST.25 (1998), Appendix 2, Table 4 showing modified and unusual amino acids, disclose a symbol corresponding to DTPA (diethylenetriamine-N,N,N',N',N-pentaacetic acid).

For the convenience of the Office, the structure of DTPA is attached hereto as an Appendix. Applicants note that DTPA does not fall within the scope of an "amino acid" and is not disclosed in any way in WIPO Standard ST.25 (1998), Appendix 2, Table 3 or Table 4. DTPA is expressly listed in the sequences shown on pages 41, 47 and 123 and is indirectly listed in the sequences shown on pages 17, 19 and 20, which explicitly list moieties "X" and "Y", either or both of which may include a chelators, such as DTPA.

According to 37 C.F.R. § 1.821(b), "Patent applications which contain disclosures of nucleotide and/or amino acid sequences, in accordance with the definition in paragraph (a) of this section, shall, with regard to the manner in which the nucleotide and/or amino acid sequences are presented and described, conform exclusively to the requirements of §§ 1.821 through 1.825." For the reasons given above, the instant application does not contain disclosures of amino acid sequences in accordance with the definition in 37 C.F.R. § 1.821(a) and are therefore not required to conform with the requirements of 37 C.F.R. §§ 1.821(a) through 1.825.

Withdrawal of the requirement is respectfully requested.

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DTPA

From Wikipedia, the free encyclopedia

Diethylene triamine pentaacetic acid (DTPA) is an elongated version of EDTA. It has been used to decontaminate humans who are contaminated with plutonium, americium and other actinides as the compound can chelate these heavy metal ions, render them unabsorbed through the digestive track and also speeds up the release of these metals in urine. It is normally used as the calcium or zinc salt. It should not be taken by people with kidney disease or bone marrow depression, nor by children younger than 18 years old. If the lungs are contaminated by the inhalation of these radioactive materials, a DTPA spray or mist is used. Otherwise it can also be injected intravenously.

Retrieved from "http://en.wikipedia.org/wiki/DTPA"

Categories: Chelating agents | Carboxylic acids | Organic compound stubs

DTPA	OH HO	O N OH	General	(Carboxymethyl)iminobis(ethylenenitrilo)]-	tetra-acetic acid	DTPA, Diethylenetriaminepentaacetic acid,	Diethylenetriamine-N,N,N',N',Pentaacetic acid,	N,N-Bis(2-(bis-(carboxymethyl)amino)ethyl)-glycine,	Pentetic acid	C ₁₄ H ₂₃ N ₃ O ₁₀	Ċ	393.3498 g/mol	White crystalline solid	[67-43-6]	Properties	? g/cm ³ , ?	<0.5g/100ml	220°C (? K)
				Systematic name		Other names			Molecular formula	SMILES	Molar mass	Appearance	CAS number		Density and phase	Solubility in water	Melting point	